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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,694	12/31/2001	Jeff T. Hutchins	07083.0008U5	1998
23347	7590	03/24/2004	EXAMINER	
DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY			SNEDDEN, SHERIDAN	
GLAXOSMITHKLINE			ART UNIT	
FIVE MOORE DR., PO BOX 13398			PAPER NUMBER	
RESEARCH TRIANGLE PARK, NC 27709-3398			1653	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/038,694

**Applicant(s)**

HUTCHINS ET AL.

**Examiner**

Sheridan K Snedden

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 1/29/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 20-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date 7/11/02; 2/20/03
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's election of invention IV, claims 9-19 is acknowledged. Claims 1-8 and 20-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper filed 29 January 2004. Claims 9-19 are under examination.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 9-19 recite fragments and derivatives of SZP. With the exception of SZP, the skilled artisan cannot envision the detailed chemical structure of the encompassed fragments or derivatives that would retain the desired functional activity. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The actual structure is required.

Therefore, only isolated SZP, but not the full breadth of the claim, meets the written description provision of 35 U.S.C. §112, first paragraph.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (US 4,894,440) in view of Warmen *et al.* (US 2002/0137894 A1), Flannery *et al.* (IDS) and Chubinskaya *et al.* (US 2002/0052358).

Rosenburg teaches MSF purified to homogeneity (7.5.times.10.sup.5 -fold) from serum-free conditioned medium obtained from cultured human embryonic kidney (HEK) cells. As a matter of fact, MSF is referenced in the art as SZP and proteoglycan 4 (see for example, Ikegawa *et al.* (IDS)).

Rosenburg does not expressly teach the use of chondrocytes (regarding claims 9 and 10).

Warmen *et al.* teach CACP, which is the same as MSF (see section [0088]). "Superficial zone protein" (SZP) is described as the bovine ortholog of CACP (see section [0088]). Figure 3 shows that chondrocytes make CACP, suggesting that bovine chondrocytes would make SZP.

Flannery *et al.* teach that SZP may be purified from bovine chondrocytes cultured in agarose in 5% solution of serum. The cells were cultured, the media harvested and the SZP was purified (see page 536, last paragraph).

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Chubinskaya *et al.* teach mammalian chondrocytes, which can be immortalized (e.g., chondrosarcoma cells) or non-immortalized (see section [0085]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use immortalized or non-immortalized chondrocytes in the method of Rosenberg *et al.* A person of ordinary skill would have been motivated to purify SZP from chondrocytes as this cell type produces SZP, and therefore, SZP would be found in the media of the cultured chondrocytes. A person of ordinary skill in the art would have expected success by culturing chondrocytes as these culturing of these cells are well documented in the art and immortalized chondrocytes are readily available. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

4. Claims 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (US 4,894,440) in view of Turner *et al.* (US 2002/0137894 A1). Rosenberg teaches MSF purified to homogeneity (7.5.times.10.sup.5 -fold) from serum-free conditioned medium obtained from cultured human embryonic kidney (HEK) cells. Rosenberg also teaches the isolation of the MSF DNA and insertion into a phage expression vector. As a matter of fact, MSF is referenced in the art as SZP and proteoglycan 4 (see for example, Ikegawa *et al.* (IDS)).

Rosenberg does not expressly teach the exogenous expression of MSF in cultured cells (regarding claims 11-19), but suggests that MSF may be produced in genetically engineered organisms, or modified MSF may be produced with altered activity.

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Turner *et al.* teach the family of MSFs. Turner *et al.* teach recombinant or genetically engineered MSFs for intracellular expression in a bacterial host, such as *E. coli* (section [0045]). The MSF proteins and the DNA sequences encoding MSFs of Turner *et al.* can be produced via recombinant genetic engineering techniques and purified from a mammalian cell line which has been designed to secrete or express the MSF to enable large quantity production of pure, active MSFs useful for therapeutic applications. The proteins may also be expressed in bacterial cells, e.g., *E. coli*, and purified therefrom. SZP purified from *E. coli* would not be glycosylated. The proteins may also be expressed and purified in yeast cells or in baculovirus or insect cells (see section [0107]).

Taken together, the above reference teaches the method of claims 11-19. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to recombinantly express MSF or SZP for the purposes of purification. The person of ordinary skill in the art would have expected success a purification of a secreted protein from the media of cultured cells is well documented in the art. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

### ***Conclusion***

5. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS

March 17, 2004

  
KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER